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TAGS: ECON EINV KIPR AR
SUBJECT: AMBASSADOR'S ROUNDTABLE WITH U.S. PHARMACEUTICALS

Ref: Buenos Aires 335

¶1. (U) The following cable contains business-confidential information and should not be distributed via internet.

SUMMARY

¶2. (SBU) Ambassador hosted a roundtable for U.S.-based pharmaceutical firms doing business in Argentina, including Pfizer; Merck, Sharp & Dohme; Bristol-Myers Squibb; Eli Lilly; Janssen-Cilag; Cardinal Health; Baxter; Abbott; Valeant; and Alcon. Company reps noted that, while their profit margins are being squeezed by heavy-handed government price controls and increasing labor costs, Argentina's pharmaceutical sector sales are growing at double digit rates. They cited flaws in Argentina's patent protection system including slow issuance of patents, poor linkage between the GoA entity approving patents and Health Ministry approval to market generic copies, and a weak legal process to fight patent infringement. Foreign-owned pharmaceuticals have sold off the bulk of their Argentine manufacturing operations over the past decade. However, their clinical pharmaceutical research has grown rapidly to take advantage of Argentina's highly educated workforce, relatively low costs, and speed of getting products into the clinical research pipeline. Companies appreciated the Ambassador's offer to advocate for improved patent protection. They argued that the best means to this end is to highlight the high-skilled and high-wage clinical research jobs U.S. pharmaceutical players provide -- the kind of jobs that speaks to Argentina's competitive advantage in higher education and the kind of jobs whose growth is directly tied to improved IP protection. End Summary.

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ARGENTINA: GETTING BETTER ALL THE TIME, BUT...
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¶3. (SBU) On April 10, Ambassador hosted a roundtable with Argentine country managers of U.S.-based pharmaceutical companies including representatives of Pfizer; Merck, Sharp & Dohme; Bristol-Myers Squibb; Eli Lilly; Janssen-Cilag; Cardinal Health; Baxter; Abbott; Valeant; and Alcon attended. (Note: Allergan, Bausch & Lomb, Schering-Plough, Wyeth and 3M were invited, but unable to attend. End Note) The Director of the research-based pharmaceutical chamber, CAEME (Argentine Chamber of Medicinal Specialties), which represnts the bulk of foreign firms operating here, also attended.

¶4. (SBU) Company reps agreed that, while margins are being squeezed due to heavy-handed government price controls and increasing labor costs, Argentina's pharmaceutical sector revenues continue to grow at double digit rates, in line with the nation's 5-year strong economic recovery. The market share of foreign-based firms has remained at roughly the 50% level, one of the lowest market shares in all of Latin America, due to GoA policies that favor local generic players who exploit weaknesses in Argentine intellectual property legislation and enforcement. While Argentina's current intellectual property (IP) regime is weak in several areas, they agreed that it is not significantly worse than IP regimes of neighboring Southern Cone countries.

¶5. (SBU) Flaws in Argentina's patent protection system include the slow issuance of patents, a lack of linkage between outstanding patents or patent applications and Health Ministry marketing approval of generic copies, and the legal process to fight patent infringement. However, there was general agreement that the most significant problem facing foreign pharmaceutical companies is the lack of data protection. In the current system, as the Abbott manager noted, companies which pirate medicines only need to present copies of marketing approval from another country (such as the

information available on the FDA website) as evidence of the safety and efficacy of their copied medications. (Note: According to the Director of ANMAT - the National Administration of Medicines, Food and Medical Technology, the Argentine FDA equivalent - his agency is required by their norms to accept that information and grant market access accordingly. End Note). Abbott's Manager also noted that the copy-makers time their submissions to take advantage of advertising by the firm which invented the medicine.

¶6. (SBU) Pfizer noted significant improvements in the review of patent applications, but noted that the average patent approval delay remains over five years. Encouraging further improvements in GoA patent processing, Pfizer argued, is the single most important area that pharmaceutical companies -- and the U.S. Embassy -- should focus on given its potential impact on the bottom lines of U.S. investors in this sector. Lilly cited their variable experience in winning court injunctions on patent infringement, including one battle which has been going on in court for two years with no success, while on ten other cases injunctions were easily obtained. The difference was that the ten cases were for molecule patents (which have only recently begun to be issued in Argentina) and the longstanding case depended on an older, process-based patent.

¶7. (SBU) On the issue of "linkage" (making marketing approval granted by health authorities contingent upon a lack of conflicting patents or patent applications), the CAEME Director stated that requiring ANMAT to adopt the practice would take a presidential decree, and there was no political will to do so. (Note: AMMAT's requirement to accept certain foreign health authority approval is based on a 1992 presidential decree. End Note).

CLINICAL RESEARCH - SUBSTITUTE FOR MANUFACTURING

¶8. (SBU) Company reps saw Argentina as a desirable place to conduct clinical research trials because of its highly educated workforce, relatively low costs, and speed of getting products into the clinical research pipeline. CAEME noted that, in 2006, its members invested approximately $100 million in such trials, of which roughly $30-40 million came from U.S. firms. CAEME firms hired approximately 5,000 clinical researchers in 2006, vs. 2,500 in 2003. Pfizer and Merck both noted that, although Argentina's skilled labor was generally superior to that found in Brazil, they would

prefer to do the same research in Brazil, since IPR protection is better there. Bristol-Myers Squibb indicated that company headquarters would likely divert new research opportunities to other countries if Argentina's IPR regime did not improve. There was broad agreement that U.S. pharmaceutical companies' investment in clinical research -- and the potential for additional investment -- offered them a point of leverage in encouraging the GoA to improve intellectual property protection.

¶9. (SBU) However, Abbott commented that, in discussions with GoA officials, they were told that the GoA favored investment in domestic "brick and mortar" production over clinical research. Many of the firms present, and other foreign-based pharmaceuticals, have sold their Argentine plants to local generic manufacturers in recent years. CAEME noted that firms in the chamber used to have a total of 35 plants in Argentina, and now own just 10. As a result, domestically owned Argentine pharmaceutical companies provide over 70% of the sector's 15,000 direct jobs.

ARGENTINE PHARMACEUTICAL SECTOR BACKGROUND

¶10. (SBU) Argentina's market for prescription pharmaceuticals totaled $2.6 billion in 2006, and has grown fairly quickly (up 16%

in 2004, 13% in 2005, and 12% in 2006). Market share by foreign-owned firms in 2006, was about 48% a share that has remained fairly constant over the past five years. Prior to the 2001/2 economic crisis, foreign owned firms had a somewhat higher, though declining, market share. Contacts have told us that Argentine domestic manufacturers hold the highest domestic market share in all of Latin America.

¶11. (SBU) This high percentage of domestic generic sales is not/not due to more competitive pricing; multinational pharmaceutical firms note that generic prices are proportionally higher here than in other countries. The high share can be attributed to the historic presence of a strong local generic industry and flaws in Argentina's IPR regime, including the ease with which illegitimate copy makers can gain health marketing approval. It is also due to the influence of their strong lobby to protect the status quo, as well as the recent shift in ownership of production facilities. Also, local firms have a solid reputation for quality, and are notably active at present (jointly with CAEME) in a campaign against "truchos" medicines (meaning "fake," but in the sense of trademark, not patent violations), some of which have contributed to serious health concerns.

¶12. (SBU) Flaws in the GoA IPR regime have hit the Argentine research-based pharmaceutical industry particularly hard. Despite fast-track procedures, difficulties in patent processing still result in long patent issuance delays, reducing the effective length of patent protection. Additionally, the 2004 patent law (passed after GOA-USG negotiations) has slowed the injunctive relief process for some firms that have found their patents violated. Under Argentine law, health regulators cannot consider the existence of any patent when making market approval decisions about a product (i.e., there is no linkage), but must accept as proof of safety and efficacy data belonging to the company that did the research. However, this information is often presented in Argentina by a company that wishes to market illegal copies, and accepting the data in such cases appears to violate the principle of "data confidentiality" found in TRIPS Article 39.3.

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Embassy Advocacy

¶13. (SBU) The companies appreciated the Ambassador's offer to support them and work on their behalf with the GoA for expanded IP protection. They said the best GoA person to approach would be Cabinet Chief Alberto Fernandez, an influential GoA insider. While the Cabinet Chief does not have GoA line authority on IP issues, they consider the normal IP interlocutors from the Industry

Secretariat in the Ministry of Economy to be wholly unsympathetic to

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foreign-based pharmaceutical company IP and pricing concerns. (Comment: Unfortunately, Fernandez is also one of the busiest GoA Ministers.)

COMMENT

¶14. (SBU) Roundtable participants offered a candid, balanced assessment of the risks and rewards of doing business in Argentina's pharmaceutical sector. They appreciated the Ambassador's offer of support, but made clear their doubt that either individual company or USG advocacy will have much impact on a GoA mindset that favors domestic capital, domestic production and large-scale employment generation. Perhaps the best means to seek better intellectual property protection for U.S. company pharmaceutical products in Argentina is to highlight the high-skilled and high-wage clinical research jobs they provide -- the kind of employment that speaks to Argentina's competitive advantage in higher education and the kind

of employment whose potential growth is linked to improved IP protection.

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